

TSCA
NEW CHEMICALS
COALITION

March 22, 2019

Via E-Mail

Jeffery T. Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC)¹ requests that the U.S. Environmental Protection Agency (EPA) change its current practices regarding direct final rulemakings for Significant New Use Rule (SNUR) notices impacting multiple chemicals to be in compliance with relevant provisions under the Code of Federal Regulations (C.F.R.). Our reasons for requesting this change are set forth below.

We are aware of and grateful for EPA staff's efforts to address the backlog of SNURs that exists and appreciate EPA's approach to issue direct final SNURs for multiple chemicals in one *Federal Register* notice. An unfortunate consequence of this approach, however, is EPA's current practice that the submission of an adverse comment on one or a few of the SNURs listed in the notice means that all of the SNURs in the notice are withdrawn. Thus, even SNURs for which no adverse comment has been submitted are withdrawn and subject to potentially long delays and significant adverse market implications before final rules can be issued for such chemicals.

We note that this EPA practice is not consistent with 40 C.F.R. Section 721.160(c)(3)(ii) and 40 C.F.R. Section 721.170(d)(4)(i)(B) concerning direct final rulemaking on "5(e)" and "non5(e)" SNURs, respectively, which states as follows:

¹ The TSCA NCC is a group of company representatives focused on working collaboratively with EPA to resolve issues of concern related to new chemical review under amended TSCA.



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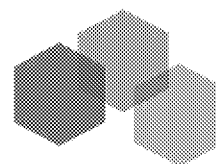
...The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER.

This procedure is also specified in the final rule implementing the direct final rule procedure:

EPA intends as much as possible to include more than one SNUR in a single Federal Register document to provide administrative efficiencies and save publication costs. With respect to direct final rulemaking procedures, when EPA publishes a number of SNURs in a single Federal Register document as direct final SNURs, the person notifying EPA of intent to submit adverse or critical comments will be asked to indicate to which SNUR the comments will apply. EPA would then publish a notice in the final rule section of the Federal Register withdrawing only that specific direct final SNUR and publish a separate proposal for that specific SNUR. However, EPA would not withdraw the direct final SNURs which are unaffected by the person's wish to submit adverse or critical comments.²

Delaying the effective date of SNURs for which no adverse or critical comments were submitted is inconsistent with the policy objectives of the direct final SNUR procedures as specified by EPA in its final rule and regulations, which EPA stated is intended to "expedite" promulgation of

² 54 Fed. Reg. 31298, 31305 (July 27, 1989).



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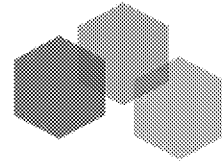
SNURs with “the objective of providing prompt promulgation of SNURs to follow-up on new chemical substances.”³

Furthermore, we do not believe that the current practice whereby some commenters offer a generic statement that the comments apply to all of the SNURs as proposed meets the requirements outlined in these C.F.R. provisions as it does not provide a clear basis for determining that an adverse comment has been submitted for all of the subject chemicals in the SNUR. 40 C.F.R. Sections 721.160(c)(3)(ii) and 721.170(d)(4)(i)(B) make clear that the adverse comments need to be specifically attached to a given SNUR(s) and that only those SNUR(s) are subject to withdrawal.

Consistent with 40 C.F.R. Section 721.160(c)(3)(ii) and 40 C.F.R. Section 721.170(d)(4)(i)(B), we request that EPA promulgate in the C.F.R. all past direct final SNURs for which no adverse comment specific to that SNUR was submitted. We understand that EPA is required to review any adverse comments submitted on the batched SNURs, but the TSCA NCC respectfully requests that this review occur as quickly as reasonably possible. We urge that EPA focus initially on identifying SNURs that were not the subject of specific adverse comment. We make this request due to the significant adverse market implications for those chemicals not implicated by any adverse comment but for which SNURs have not yet been issued in final.

In a related matter, the TSCA NCC has observed how the legal effect of SNURs for both new and existing chemicals has been widely misunderstood and mischaracterized by stakeholders and the general public. The recent asbestos SNUR is a good example. In the general and trade press, it has been characterized by some as “allowing” new asbestos uses. This, as you know, is an erroneous and misleading statement of the purpose and effect of a SNUR. Considering the changes in amended TSCA Section 5(a) that now require EPA to review a significant new use notification (SNUN), make a determination, and take the actions required in association of that determination, we encourage EPA to develop and use a clearer and legally accurate characterization of the effect of SNURs in its written materials, including in *Federal Register* notices that propose or promulgate SNURs, including expedited SNURs. We offer the following suggestions as ways to characterize more clearly the legal effect of SNURs and defend against intentional or unintentional mischaracterization of SNURs:

³ *Id.* at 31299.



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- The SNUR identifies conditions of use that are prohibited absent EPA review of a notification that such use is contemplated and its determination that such use can proceed and, if so, under what circumstances.
- The legal effect of a SNUR is to prohibit subject conditions of use absent completion of the steps required by Section 5(a). These requirements include submission to EPA of a notification, followed by EPA's review and determination under Section 5(a)(3) on the notified significant new uses, and any EPA actions required in association with that determination. Absent a determination that the significant new use is "not likely to present an unreasonable risk," EPA is required to regulate to the extent necessary to protect against such risk.

Thank you for your consideration of the legal and policy arguments raised in this letter. We would appreciate an opportunity to meet with you and other EPA staff to discuss the specific recommendations outlined above. I will contact you in the near future to identify potential meeting dates.

Sincerely,

Kathleen M. Roberts

cc: Nancy B. Beck, Ph.D., DABT (via e-mail)
Alexandra P. Dunn, Esquire (via e-mail)